## In the United States Court of Federal Claims

### OFFICE OF SPECIAL MASTERS

No. 20-0482V UNPUBLISHED

CHRIS MCMULLEN.

Petitioner.

٧.

SECRETARY OF HEALTH AND HUMAN SERVICES.

Respondent.

Chief Special Master Corcoran

Filed: July 8, 2022

Special Processing Unit (SPU); Table Injury Dismissal; Tetanus, Diphtheria, acellular Pertussis (Tdap) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA); Onset of Shoulder Pain

Maximillian J. Muller, Muller Brazil, LLP, Dresher, PA, for Petitioner.

Mallori Browne Openchowski, U.S. Department of Justice, Washington, DC, for Respondent.

# FINDINGS OF FACT AND CONCLUSIONS OF LAW DISMISSING TABLE CLAIM 1

On April 21, 2020, Chris McMullen filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*<sup>2</sup> (the "Vaccine Act"). Petitioner alleged that he suffered a left shoulder injury related to vaccine administration ("SIRVA"), a defined Table Injury, after receiving a tetanus-diphtheria-acellular pertussis ("Tdap") vaccine on November 7, 2018. Petition at 1, ¶ 3. He further

<sup>&</sup>lt;sup>1</sup> Because this unpublished Fact Ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Fact Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

<sup>&</sup>lt;sup>2</sup> National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

alleged that his "symptoms began within forty-eight (48) hours of vaccination and lasted for more than six (6) months." *Id.* at 1; *accord. Id.* at ¶ 14.

For the reasons discussed below, a preponderance of the evidence supports the conclusion that the onset of Petitioner's left shoulder pain occurred later than 48 hours post-vaccination – meaning he cannot establish the onset required for his Table SIRVA claim, and therefore the Table claim must be dismissed (although a causation-in-fact version of the claim could succeed).

#### I. Relevant Procedural History

Along with the Petition, Mr. McMullen filed a vaccine record showing he received a Tdap vaccine intramuscularly on November 7, 2018, and an affidavit addressing the basic requirements for compensation under the Act. Exhibits 1-2, ECF Nos. 1-4 through 1-5. Approximately two weeks later, he filed the medical records required under the Vaccine Act. Notice of Filing for Exhibit 3, filed by CD on May 4, 2020, ECF No. 5; see Section 11(c). These medical records contained a more comprehensive vaccine record, indicating the Tdap vaccine was administered in Petitioner's left deltoid as alleged. Exhibit 3 at 2. After the certification for these records was filed on July 30, 2020 (Exhibit 4, ECF No. 11), the case was activated and assigned to SPU. ECF No. 13.

On December 9, 2020, Petitioner forwarded a demand and supporting documentation to Respondent as instructed. Status Report, filed Feb. 19, 2021, ECF No. 19. On August 19, 2021, Respondent agreed to engage in settlement discussions. ECF No. 21. However, after three months, the parties informed me they had reached an impasse. ECF No. 26.

Approximately one month later, on December 21, 2021, Respondent filed his Rule 4(c) Report, opposing compensation in this case. ECF No. 27. Specifically, Respondent argued that "[P]etitioner has not demonstrated that his pain began within 48 hours of vaccination" as required for a Table SIRVA injury. *Id.* at 5. In reaction, on January 18, 2022, I issued an order to show cause, allowing Petitioner a final chance to obtain and to file the evidence needed to support his allegations regarding the onset of his alleged SIRVA injury. ECF No. 28. I also "instruct[ed] the parties to make one last attempt to engage in settlement discussions." *Id.* at 7.

On February 22, 2022, the parties filed a joint status report indicating they "[we]re unlikely to reach a settlement agreement, . . . [and] Petitioner intends to submit additional evidence and a response to the Order to Show Cause." ECF No. 29. Petitioner provided

his response on April 20, 2022. Petitioner's Brief in Response to Order to Show Cause ("Pet. Response"), ECF No. 31.

#### II. Issue

At issue is whether Petitioner's first symptom or manifestation of onset after vaccine administration (specifically pain) occurred within 48 hours as set forth in the Vaccine Injury Table and Qualifications and Aids to Interpretation ("QAI") for a Table SIRVA. 42 C.F.R. § 100.3(a) I.C & II.C. (2017) (Tdap vaccination); 42 C.F.R. § 100.3(c)(10)(ii) (required onset for pain listed in the QAI).

#### III. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475, at \*20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. "Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 74931, \*4 (Fed. Cl. Spec. Mstr. April 25, 1991), quoted with approval in decision denying review, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed.Cir.1992)). And the Federal Circuit recently "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

The United States Court of Federal Claims has outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that

happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Hum. Servs.*, 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808, 1998 WL 408611, at \*5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such fact testimony must also be determined. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

#### IV. Relevant Factual Evidence

A review of the medical records and other evidence filed in this case shows Petitioner suffered a right shoulder SLAP<sup>3</sup> tear in 2010 which continued to cause him pain as late as 2016 (Exhibit 3 at 29-45) and complaints of neck and upper back pain less than six months prior to vaccination in May and August 2018 (*id.* at 100-11, 126-40).<sup>4</sup> There is

<sup>&</sup>lt;sup>3</sup> SLAP stands for Superior Labrum Anterior Posterior. MEDICAL ABBREVIATIONS at 552 (16<sup>th</sup> ed. 2020).

<sup>&</sup>lt;sup>4</sup> Prior to vaccination, Petitioner also suffered from depression (Exhibit 3 at 3-45, 112-25), neck pain in 2015 (*Id.* 418-45), and right hand and wrist pain in late 2016 and early 2017 (*id.* at 46-99).

no evidence that he suffered any prior *left* shoulder pain, however. As noted, he received the Tdap vaccine on November 7, 2018.

Petitioner first sought treatment for left shoulder pain from his primary care provider ("PCP") more than two months post-vaccination on January 14, 2019. Exhibit 3 at 141-44. At that initial visit, he complained of "moderately severe left shoulder pain," "present for 1.5 months 's/p<sup>[5]</sup> flu<sup>[6]</sup> shot." *Id.* at 141. He reported that the pain was "aggravated by abduction and rotation." *Id.* Upon examination, the PCP observed no swelling, redness, or tenderness but "[I]imited abduction and internal rotation." *Id.* at 142. He prescribed Tylenol with codeine and provided referrals for physical therapy ("PT") and to a pain management clinic. *Id.* at 143.

The same description of Petitioner's left shoulder pain is found in the medical record from his January 26<sup>th</sup> visit to the pain management clinic. Exhibit 3 at 158. Under consultation, "progressive L shoulder pain and weakness s/p flu shot" is listed. *Id.* Referencing Petitioner's earlier right shoulder SLAP tear diagnosis, the treating physician noted that Petitioner now ha[d] symptoms on the left side and is worried about having a rotator cuff tear of slap lesion." *Id.* at 161. The treating physician ordered an MRI, agreed Petitioner should begin PT, and administered a cortisone injection. *Id.* at 160-62. The MRI, performed on February 9<sup>th</sup>, showed mild tendinopathy without tearing, slight arthrosis, and mild degeneration of the biceps anchor, but "no significant bursal fluid and/or inflammation." *Id.* at 164.

At his first PT session on February 1, 2019, Petitioner reported "developing L shld pain since TDAP shot in November." Exhibit 3 at 177. After three sessions, Petitioner was discharged from PT on March 1<sup>st</sup>, for a failure to return for treatment. *Id.* at 212. It was noted that Petitioner's PCP had authorized PT through April 1, 2019. *Id.* 

Following two of the three PT sessions he attended and two days prior to his discharge from PT, Petitioner visited an orthopedist, complaining of "left shoulder pain since November." Exhibit 3 at 199. At this February 28<sup>th</sup> visit, he described "[m]inimal pain at rest" in his lateral shoulder which radiated down his arm and was worse with abduction. *Id.* After reviewing Petitioner's February 9<sup>th</sup> MRI, the orthopedist diagnosed him with a "ligament injury possibl[y] a bucket handle tear." *Id.* at 198. Mentioning his "prior history

<sup>&</sup>lt;sup>5</sup> S/P stands for status post. MEDICAL ABBREVIATIONS at 552.

<sup>&</sup>lt;sup>6</sup> In his affidavit, Petitioner insists that he was misquoted, maintaining that he indicated the Tdap, rather than the flu, vaccine. Exhibit 6 at ¶ 4. The medical records show that Petitioner also received an influenza ("flu") vaccine on September 4, 2018, two months prior to receiving the Tdap vaccine alleged as causal. Exhibit 3 at 1. It also was administered in his left deltoid. *Id.* 

of right shoulder having a slap lesion," he recommended Petitioner undergo an arthrogram. *Id.* 

Approximately one month later, on April 3, 2019, Petitioner was seen at the urgent care clinic, complaining of back pain for two days after recent heavy lifting. Exhibit 3 at 220. It was noted that he had a "[p]rior history of back problems: recurrent self-limited episodes of low back pain in the past." *Id.* He was diagnosed with lumbar muscle strain and instructed to apply heat and to take muscle relaxers. *Id.* at 221. He was seen by his PCP for his lower back pain two times in May 2019. *Id.* at 230, 245.

Petitioner returned to the orthopedist on May 30, 2019. Exhibit 3 at 257. At that visit, he again described moderate left shoulder pain since November 2018. However, next to "[m]echanism of injury," it is noted that Petitioner had "no hx of trauma." *Id.* Petitioner reported that the January cortisone injection "helped [for] about 2.5 months and his shoulder is now about the same as it was before the injection." *Id.* After reviewing the earlier MRI, performed on February 9, 2019, the orthopedist amended his earlier opinion, now stating that he believed a "[d]isplaced bucket-handle tear is thought to be less likely," but reiterated his belief that an MRI arthrogram would be helpful. *Id.* at 260. The orthopedist administered a second cortisone injection and recommended that Petitioner continue his home exercise program. *Id.* 

A few weeks later, Petitioner was seen at the pain management clinic for his lower back pain. Exhibit 3 at 270. It appears that he received multiple trigger point injections. *Id.* at 274. At his next orthopedic visit on August 30, 2019, Petitioner reported that he obtained two months of relief from the second cortisone injection. Exhibit 3 at 285-86. Although interested in surgery, he indicated that it currently was not a good time due to his work. *Id.* at 286. Petitioner eventually underwent surgery in late November 2019. Exhibit at 328-37. He attended follow-up orthopedic appointments and PT during December 2019 through mid-January 2020. *Id.* at 339-415.

In addition to the information contained in his medical records, Petitioner has provided a second affidavit and a one-page screen shot of written communications with his finance during the morning of January 3, 2019, approximately two months post-vaccination. Exhibits 5-6. In the affidavit, executed on September 28, 2021, Petitioner described receiving the Tdap vaccine on November 7, 2018, indicating it was administered "high up on [his] left deltoid" while seated and reporting that he "immediately felt pain in [his] upper deltoid." Exhibit 6 at ¶ 1. In the January 9<sup>th</sup> message to his finance, Petitioner wrote the following:

Yeah, just tired. I've been looking up my shoulder pain and I'm pretty sure it was caused by my last immunization. I got a Tdap shot in November and it has hurt ever since. I'm finding several things online about vaccine related shoulder injuries. Going to see my doctor in a few weeks.

Exhibit 5 at 1. In this one-page screen shot, containing only a portion of the entire conversation, the word Tdap is highlighted. *Id.* 

#### V. Parties' Arguments

When asserting that Petitioner has failed to establish the onset required for a Table SIRVA injury, Respondent emphasizes the following:

- 1. the two-month delay between vaccination and the date he first complained of left shoulder pain;
- 2. the January 2019 entries describing his left shoulder pain as present for one and a half months and occurring after the flu, rather than Tdap, vaccine; and
- 3. the lack of specific language in the medical records identifying exactly when onset occurred.

Rule 4(c) Report at 5. He stresses that "Petitioner did not advise a medical provider that his pain began after a *Tdap* vaccination until he presented to PT on February 1, 2019." *Id.* (emphasis added). Regarding the screenshot of the Facebook Message communication between Petitioner and his finance, Respondent observes that it was produced with a date stamp, but no accompanying metadata to confirm its date of creation. *Id.* at 5 n.7.

Countering Respondent's arguments, Petitioner insists that "[t]he record, as a whole, supports immediate onset." Pet. Response at 9. He contends that "the only record that suggests a non-immediate onset of symptoms" is the entry regarding onset contained in the medical record from the January 14, 2019 visit to his PCP. *Id.* at 10. Mentioning several entries describing left shoulder pain since vaccination (*id.* at 10-11), Petitioner maintains the record from January 14<sup>th</sup> "is ambiguous at best, and wholly inconsistent with the other descriptions of onset in the record." *Id.* at 11.

#### VI. Findings of Fact and Dismissal of Table Claim

As I stated in my previous order, a two-month delay in treatment is, by itself, unremarkable. In vaccine injury cases, it is common for individuals who have experienced a vaccine-caused SIRVA to delay treatment, thinking his/her injury will resolve on its own. However, when treatment is sought, these individuals usually provide detailed descriptions of the onset of their pain, and display a conviction that their pain was linked to the vaccination they received.

In this case, Petitioner showed some hesitancy regarding the cause of his pain – indicating in early January, for example, that he was "pretty sure" it was caused by the Tdap vaccine after performing research on the internet. Exhibit 5 at 1. It is illogical to believe he would have not reached that conclusion earlier if he had experienced the immediate pain he described in his later affidavit. Exhibit 6 at ¶ 1. More significantly, when he first sought treatment on January 14, 2019 – approximately ten days later and two months post-vaccination - Petitioner reported that the pain had been *present* for only 1.5 months, placing onset at the end of November 2018. Exhibit 3 at 141, 158.

Petitioner argues that this initial report is an outlier, inconsistent with the remainder of the evidence, but that characterization is incorrect. Although the medical records contain some entries referring to pain *since* or *post status* vaccination – including the record in question - none provide a more detailed or earlier depiction of pain onset. And there are multiple entries showing that the onset of Petitioner's pain was gradual. Thus, it was described as "progressing" in late January 2019, and then "developing" at his first PT session on January 1, 2019. *Id.* at 158, 177. Petitioner's January 14<sup>th</sup> report of pain which began in late November 2018 aligns with these later medical records.

The record in this case supports a finding that the onset of Petitioner's pain developed gradually, beginning in late November 2018. It does not support Petitioner's assertion of an *immediate* pain onset close-in-time to his receipt of the Tdap vaccine. Petitioner has thus failed to provide evidence to establish onset within 48 hours of vaccination as required for a Table SIRVA injury.

#### VII. Potential for Off-Table Claim

A petitioner's failure to establish a Table injury does not necessarily constitute the end of a case under all circumstances, because he or she might well be able to establish a non-Table claim for either causation-in-fact or significant aggravation. See Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274 (Fed. Cir. 2005); W.C. v. Sec'y of Health

& Human Servs., 704 F.3d 1352, 1357 (Fed. Cir. 2013) (citing Loving v. Sec'y of Health & Human Servs., 86 Fed. Cl. 135, 144 (2009)).

Here, it is conceivable that Petitioner may be able to prove that the Tdap vaccine caused his left shoulder pain injury, despite the delayed and gradual onset described in the medical records. However, he must establish a causal link and appropriate time frame between the Tdap vaccine he received and his left shoulder pain. Formal resolution of this issue will likely require further review and most likely the retention of experts, which I am not inclined to authorize in the SPU. Moreover, this case has already been pending in the SPU for almost two years – meaning it is inadvisable to allow it to stay in SPU any longer. Thus, the claim may go forward as a causation-in-fact claim – but it may no longer remain in SPU.

#### VIII. Conclusion

Petitioner has not established the onset of his left shoulder pain occurred within 48 hours of his receipt of the Tdap vaccine on November 7, 2018. Accordingly, his Table SIRVA claim is dismissed. Pursuant to Vaccine Rule 3(d), I will issue a separate order reassigning this case randomly to a Special Master.

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran Chief Special Master